DMB

Display Date 4-20-01
Publication Date 4-23-01
Certifier SRRC

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0162]

Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements." This draft guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements directed toward consumers (DTC) in print media contain adequate risk disclosure. FDA does not intend to object to the use of certain FDA-approved patient labeling, reprinted exactly as approved, to fulfill the requirement that DTC print advertisements contain a brief summary of the product's risks.

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests

NAD 1

to 800–835–4709. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD–42), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828.

Regarding prescription human biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements." The draft guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements DTC in print media contain adequate risk disclosure.

The requirement that all prescription drug and biological product advertisements disclose product risks comes from section 502(n) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(n)). This section of the act requires that advertisements for prescription drugs and biological products include a true statement of information "in brief summary" about the benefits and risks of using the advertised product. This is often called the "brief summary" requirement. The prescription drug advertising regulations (21 CFR 202.1(e)(3)(iii)) specify that the information about risks include every risk in the advertised drug's approved product labeling.

Some prescription drug and biological products have FDA-approved patient labeling that contains information that is most important for the safe and effective use of these products in language consumers are likely to understand. The draft guidance specifies that FDA does not intend to object to the use of certain FDA-approved patient labeling, reprinted exactly as approved, to fulfill the brief summary requirement for DTC print advertisements. The draft guidance describes the characteristics that such patient labeling should have to be used to fulfill the brief summary requirement.

This draft guidance is being issued as a level 1 guidance, consistent with FDA's good guidance practices regulations (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on using FDA-approved patient labeling in DTC print advertisements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm and at http://www.fda.gov/cber/guidelines.

Dated: April 17, 2001

April 17, 2001.

Ann M. Witt,
Acting Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160–01–S